## AMENDMENTS TO THE DRAWINGS

Enclosed are seven Replacement Sheets containing Figs. 1-8. These seven Replacement Sheets contain formal drawings.

Attachments: Seven Replacement Sheets containing Figs. 1-8, which are formal drawings.

## REMARKS

Applicant's counsel thanks the Examiner for the careful consideration given the application. Claims 1-4 have been amended; claims 5-8 have been cancelled; claim 9 is original; claims 10-16 have been withdrawn and claims 17-24 are new.

Amended claim 1 corresponds to original claims 1+5+6+7+8 and description page 6, lines 14-16 and description page 17, lines 27-32.

Amended claims 2-4 correspond to original claims 2-4 where "in which" has been substituted with "wherein" for clarity.

Original claims 5-8 have been deleted.
New claim 17 is based on page 9, line 5.
New claim 18 is based on page 8, lines 3-5.
New claim 19 is based on page 9, line 6.
New claim 20 is based on page 9, line 7.
New claim 21 is based on page 9, lines 13-14.
New claim 22 is based on page 9, line 14.
New claim 23 is based on page 7, lines 4-11.
New claim 24 is based on page 7, lines 15-21.
Therefore no new matter has been added.

In response to paragraphs 2-10 of the Office action, the specification and claims have now been amended accordingly.

**Claim Rejection - 35 USC § 102**

The claims have been rejected under Sec. 102 as anticipated by Nyilas (US 3562352) and Kira (US 4623347).

US 4,623,347 (US'347) shows polydimethylsiloxane having formula as at column 6, line 5 and in claim 5.

US'347 does not show or suggest polydimethylsiloxane having acetoxy groups.

Therefore, it is concluded that amended claim 1 is novel over US'347.

The poly(dimethylsiloxane) shown in US 3,562,352 (US'352) is acetate end-block and has 8 terminal groups per molecule, column 5, lines 74-75.

US'352 does not show or suggest polydimethylsiloxane having four terminal acetoxy groups, two for each terminal chain portion as claimed in the present amended claim 1.

Therefore, it is concluded that amended claim 1 is novel over US'352 as well.

Therefore the Examiner's objections in paragraphs 11-13 of the Office action have now been overcome.

**Claim Rejection - 35 USC § 103**

The most relevant prior art document is represented by US'352.

The difference between amended claim 1 and US'352 is given by the technical feature: "... a polydimethylsiloxane having four terminal acetoxy groups, two for each terminal chain portion.".

In this regard Applicant points out that US'352, column 5, lines 74-75, discloses that: "The poly(dimethylsiloxane) was acetate end-blocked and had 8 (eight) terminal groups per molecule".

The polydimethylsiloxane claimed in the present amended claim 1 has four terminal acetoxy groups, two for each terminal chain portion.

The advantage (technical effect) conferred by the difference is that the elastomeric material shows a three-dimensional network (reticulation of chemical bonds) due to the presence of tetraacetoxy-functionalized polydimethylsiloxane. In practice, two terminal acetoxy groups that are present in polydimethylsiloxane bind as a bridge between two backbones (two urethane chains), as shown in Figure 1.

This advantage is clearly shown by the present application at page 9, figures 1, 2 and 3: "In practice, the reaction conditions within the reactor, for instance a three-neck reactor (temperature, stirring and nitrogen ambient to avoid moisture) are such that the functionalized

polydimethylsiloxane reacts with the hydrogen atoms of the urethane portions that are present in polyurethane chain. The formation of chemical bonds creates a reticulation. In practice, two acetoxy groups that are present in polydimethylsiloxane bind as a bridge between two backbones (two urethane chains), as shown in Figure 1."

"Figure 1 shows the reticulation occurring in the polyurethane chain through the formation of the bond with the tetraacetoxy functions that are present in tetra-functionalized polydimethylsiloxane."

"Then, during the polymerization of the material (by casting or spraying) the remaining amount of tetraacetoxy-functionalized polydimethylsiloxane, in presence of atmospheric humidity or water, reacts and gives rise to a condensation reaction. Such condensation reaction turns the silicone "pre-polymer" into a polymer with a higher molecular weight (elastomeric material)."

"The reaction byproduct is acetic acid obtained from the reaction mechanism and from the reticulation of polydimethylsiloxane as schematically shown in Figures 2 and 3."

"Figure 2 shows the reticulation mechanism of tetraacetoxy-functionalized polydimethylsiloxane."

"Figure 3 shows the formation of a three-dimensional network (reticulation of chemical bonds) due to the presence of tetraacetoxy-functionalized polydimethylsiloxane.".

The elastomeric material of the present invention is obtained through a synthesis process resulting in an interpenetrating polymeric network, page 13, line 29-31.

The particular structure (an interpenetrating polymeric network) combines the excellent chemical-physical properties of polyurethane with the properties of biostability and hemocompatibility of silicone, from page 13, line 32 to page 14, line 2.

The elastomeric material claimed in amended claim 1 shows an improved hemocompatibility, biostability and tissue compatibility.

The in vitro citotoxicity tests of the application show that the specific elastomeric material is not toxic, from page 15, line 24, to page 16, line 33: "The results of in vitro citotoxicity tests obtained with the elastomeric material according to the present invention are compared with those of the polymers used as reference, and indicate that the new material is not toxic.

The lack of toxicity is further confirmed by in vivo tests carried out in the intramuscular system (rabbit's paraventral muscle) and involving the incorporation of material strips for one week (ISO 10993-6, Tests for local effects after implantation).

The potential inflammatory reaction caused by the implantation made with the material according to the present invention, containing various percentages of silicone PDMS, has been evaluated through tests involving the incorporation of material strips into rabbit's paravertebral muscle for periods varying from 8 to 12 months.

The histological (hematoxylin-eosin) and immuno-histochemical (through monoclonal antibodies directed against inflammatory cells, in particular macrophages) analysis of tissue surrounding the implantation site have pointed out the absence of inflammatory reactions for the material according to the present invention with silicone percentages of 20, 30 and 40%, whereas both lower and higher percentages have resulted in quite a remarkable reaction.

Biostability has been evaluated through the implantation of strips of the material, both as such and after 100% stretch, into rat's dorsal-lumbar region. The samples explanted and analyzed through SEM and FT-IR have shown an absence of biodegradation for silicone contents of 30 and 40% with respect to higher and lower percentages. Vascular prostheses carried out with the composition according to the present invention have been tested for hemocompatibility through in vitro tests involving human blood circulation and implantation of sheep's carotid artery by-pass. In vitro tests with the elastomeric material containing different percentages of silicone take into consideration some parameters concerning adhesion and platelet activation. The results have identified the elastomeric material containing 30 to 40% of silicone as the least thrombogenic. This elastomeric material has been chosen for the subsequent in vivo implantations.".

The technical problem to be solved is to provide elastomeric materials with improved hemocompatibility, biostability and tissue compatibility.

The above objective technical problem is solved by the elastomeric material as claimed in the present invention.

Neither US'352 nor US'347 showed or suggested to use the specific polyetherurethane-polydimethylsiloxane elastomers to improve hemocompatibility, biostability and tissue compatibility.

Accordingly, it is clear that it was not obvious for a person of ordinary skill to arrive at the claimed process and materials.

For all the foregoing reasons, it is clear that the claims as now presented clearly define over the art of record and are now in condition for allowance, which is respectfully requested.

If any additional fees are required by this communication, please charge such fees to our Deposit Account No. 16-0820, Order No. 36159.

Respectfully Submitted,

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